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Guidance for the Reregistration of Pesticide Products Containing Arsenic Acid (Non-Wood Preservative Uses) as the Active Ingredient

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GUIDANCE FOR THE
REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

ARSENIC ACID
(NON-WOOD PRESERVATIVE USES)

AS THE ACTIVE INGREDIENT

CHEMICAL CODE: 006801

CASE NUMBER: GS-0389

CAS REGISTRY NUMBER: 7778-39-4

SEPTEMBER 1986

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard. Pesticides have been grouped into use clusters and will be reviewed on the basis of a ranking scheme giving higher priority to (1) pesticides in clusters used on food and feed crops; and (2) pesticides produced in large volumes.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division, (TS-757C), EPA, 401 M St., SW, Washington, D.C. 20460.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as proposed cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in Tables A, B, and C of Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

FIFRA sec. 6(a)(2) requires registrants to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. DESCRIPTION OF CHEMICAL

The following chemical is covered by this Registration Standard:

Common name: Arsenic acid
Chemical name: Arsenic Acid, Orthoarsenic acid
CAS Number: 7778-39-4
OPP (Shaughnessy) Number: 006801
Empirical Formula: H_3AsO_4
Trade names: Desiccant L-10®, Hi Yield® H-10, Poly Brand Desiccant, Hi Yield® Synergized H-10®
Description of physical characteristics of chemical [Note - Information listed refers to the pure active ingredient, unless specified as technical grade active ingredient (TGAI)]:

Physical State-- Aqueous solution (TGAI)
Color-- Pale yellow to pale green (TGAI)
Odor-- None (TGAI)
Boiling Point-- Not available in Agency files.
Flash Point-- Not available in Agency files.
Melting Point-- Not available in Agency files.
Solubility-- Highly soluble in water (TGAI)
Specific Gravity-- 1.884 at 20°C (TGAI)
Stability-- Reacts with bases to form salt (TGAI)
Unusual Handling Characteristics-- Reacts with fabric, galvanized metals, black iron, and certain other metals resulting in deterioration, corrosion, or liberation of gases (e.g., hydrogen, arsine).

B. COMPOSITION OF INORGANIC ARSENIC COMPOUNDS

Arsenic acid (H_3AsO_4) is an inorganic form of arsenic. Arsenic exists in two oxidation or valence states, As^{+3} (trivalent) and As^{+5} (pentavalent). Arsenic acid is pentavalent. Salts of arsenic may be pentavalent arsenates or trivalent arsenites. Inorganic arsenic compounds (arsenicals) can be transformed chemically between trivalent and pentavalent inorganic forms depending upon environmental conditions. Inorganic and organic forms (combined with carbon atoms) are also interconverted in nature. In animals, similar transformations occur during metabolism in the body. Refer to Section III.B.2. for a discussion of the metabolism of arsenicals in animals.

C. USE PROFILE

Type of Pesticide: Desiccant

Pests Controlled: N/A

Registered Uses: Cotton, Okra (seed production crop only)

Predominant Use: Cotton

Mode of Activity: Desiccation of foliage and stems

Formulation Types Registered: Aqueous solutions (end use only)

Method(s) of Application: Foliar spray (single application prior to harvest)

D. REGULATORY HISTORY

The principal use of arsenic acid as a pesticide has been as a component of wood preservative formulations. These are not addressed in this Registration Standard, but will be subject of a separate Registration Standard concerning chromated arsenicals. The uses of arsenic acid subject to this registration standard are desiccant uses on cotton and okra seed crop.

Arsenic acid has been registered as a cotton desiccant for over 22 years. In 1979, a non-food use on seed crop okra was registered in the state of Arizona. Previously registered nonwood preservative uses also included use as a broad spectrum herbicide on Bermudagrass turf and noncrop areas (e.g., highway and rail rights-of-way, parking lots, drainage ditchbanks). All but the cotton and okra uses have been voluntarily cancelled.

The Environmental Protection Agency issued a Notice of Rebuttable Presumption Against Registration (hereafter referred to as Special Review) for the wood preservative and non-wood preservative uses of the inorganic arsenicals on October 18, 1978 (43 FR 48267). That notice was based on a determination that the use of the inorganic arsenical pesticide products met or exceeded the risk criteria for oncogenicity, mutagenicity and teratogenicity under 40 CFR 162.11 (these risk criteria are now found in 40 CFR 154.7).

In January 1981, the Agency issued a preliminary regulatory determination (46 FR 13020) which proposed changes to the terms and conditions of registration for the wood preservative uses of the inorganic arsenicals. The non-wood preservative products were not included in this proposed decision, but will be the subject of a separate proposed decision in the future.

III. AGENCY ASSESSMENT

A. SUMMARY

The Agency has reviewed all the data submitted to support the registration of arsenic acid as well as a number of pertinent studies in the open literature on arsenic acid and certain other inorganic arsenicals (e.g., sodium arsenate, sodium arsenite, arsenic trioxide, arsenic pentoxide). Based on a review of these data, the Agency has determined the following (see Section B of this Part for more detailed information):

1. Arsenic acid is acutely toxic to humans by the oral route, as observed from its use in homicides, suicides and poisonings. Few animal tests have been conducted for acute toxicity, however, and data are required on formulated products of arsenic acid.

2. Inorganic arsenic compounds (including arsenic acid) have been classified as Group A oncogens, signifying that there is sufficient evidence of human oncogenicity, based on human epidemiological studies. This conclusion is supported by evidence of mutagenicity in numerous studies.

Excess mortality due to lung cancer was demonstrated in several studies among smelter workers and among workers engaged in the production of arsenical pesticides. Other human epidemiology studies have demonstrated an association between exposure to high levels of arsenic in drinking water or in arsenic containing medicinal preparations and skin cancer.

An inhalation risk assessment indicates that the risks to mixer/loaders and applicators of arsenic acid are comparable to those that have been tolerated for the general population in the vicinity of smelters due to arsenic in the ambient air. At this time the Agency is unable to estimate dermal or dietary risks from arsenic acid pesticide uses. The EPA Risk Assessment Forum is reevaluating the appropriate risk model to be used for these routes of exposure to arsenic.

3. Arsenic has demonstrated a potential to cause teratogenic or fetotoxic effects. The Agency has determined, however, that existing animal studies on inorganic arsenicals are inadequate for risk assessment purposes. Therefore additional teratogenicity tests are necessary. The Agency issued a Data Call-In (DCI) Notice on 4/7/86 requesting teratogenicity data for inorganic arsenical wood preservatives.

4. The use of arsenic acid as a desiccant on cotton in Texas coastal counties may affect the Attwater's Greater Prairie Chicken, an endangered species. The chicken feeds in and around cotton fields from July to September and may ingest arsenic acid-contaminated vegetation, seeds and insects. Arsenic acid has been added to the group of pesticides used on cotton currently being reviewed by the Office of Endangered Species, U.S. Department of Interior. Labeling statements will be required on an interim basis until avian acute toxicity and avian feed residue studies are received and evaluated.

B. PRELIMINARY RISK ASSESSMENT.

There is an extensive body of information available on arsenic and its inorganic compounds from literature and other sources. Therefore, although the Agency does not have specific studies on arsenic acid per se, in many cases it is not requiring additional data under FIFRA. This risk assessment relies primarily on studies and documents developed for other Agency purposes. Principal among these is a final report of the Agency's Office of Health and Environmental Assessment (OHEA), entitled "Health Assessment Document for Inorganic Arsenic." This and other documents mentioned are cited in the Bibliography (Appendix IV).

1. Acute toxicity. The acute oral toxicity of inorganic arsenicals in humans has been well documented over centuries of use as a poison in homicides, suicides, and from accidental ingestion of drugs and pesticides. The pentavalent forms are less toxic than the trivalent ones; however, the symptoms of toxicity are the same. The reported oral toxicity of arsenic acid in rats is 48-100 mg/kg, however, the rat is a poor model for toxicity in man, since it binds arsenic in the body. Man is known to be more sensitive than the rat to arsenic poisoning on a weight basis.

Data on dermal and inhalation systemic toxicity and skin and eye irritation potential of arsenic acid are not available and are required to be submitted.

2. Metabolism. The in vivo metabolism of inorganic arsenicals is well understood. The development of new analytical techniques capable of identifying the forms of arsenic in the body has enabled researchers to chart the biotransformations that occur. In every mammalian system studied, inorganic arsenicals are metabolized from the pentavalent forms (arsenic acid, sodium arsenate) to the trivalent arsenite form. At the same time, a methylation process results in the formation of monomethyl and particularly dimethyl arsenic compounds. These are subsequently excreted in the urine, usually within several days.

With the exception of rats, arsenic does not generally accumulate in active tissues of the mammalian body. Retention of arsenic in skin, hair, and nails is regarded as an excretory mechanism. Rats, however, bind arsenic to erythrocytes, which results in a delayed distribution to tissues and a biological half-life of up to 90 days. For this reason, studies using rats as the test species give atypical results. Required testing is to be conducted with species other than the rat to avoid anomalous findings.

3. Carcinogenicity. The Carcinogen Assessment Group (CAG) of the Environmental Protection Agency has performed an assessment of the weight of evidence for carcinogenicity of inorganic arsenicals. Based on epidemiological studies in humans and on other supportive studies and information, the CAG concluded there is sufficient evidence that inorganic compounds of arsenic are both lung and skin carcinogens in humans. According to the Agency's draft Guidelines for Carcinogen Risk Assessment (January 7, 1986) inorganic arsenicals (including arsenic acid) have been classified in Group A (carcinogenic to humans).

A large number of toxicological studies are available on the oncogenicity of arsenic compounds. The most critical and persuasive evidence linking human cancer with exposure to inorganic arsenicals was derived from epidemiology studies. An excess mortality due to lung cancer associated with exposure to arsenic was demonstrated in several studies of smelter workers and among workers engaged in the production of arsenical pesticides. The increased mortality in these studies was related to occupational inhalation exposure to inorganic arsenicals.

Among the numerous available studies, the CAG based a final risk model for occupational inhalation exposure on three studies of copper smelter workers and on an NCI series of statistical analyses of some of these same workers:

a. Higgins et al. (1982) conducted a followup study on smelter workers in Anaconda, Montana, who had previously been studied by Lee and Fraumeni in 1969. The Higgins study contains data on 1800 men, including all of the heavy exposure workers and 20% of the other workers from the Lee and Fraumeni study. Cumulative exposures were estimated and information on smoking habits was obtained for most of the cohorts. A statistically significant increase in the number of respiratory cancers was observed among non-smokers in the high exposure group. This study is summarized in the OHEA report, pp. 7-104 to 7-110.

b. Lee-Feldstein (1983) surveyed 8047 smelter workers at the same location as Higgins et al. in Anaconda, Montana. This large study followed mortality for up to 39 years among workers who had been employed for at least 12 months. Workers were categorized into heavy, medium and light exposure groups and by length of employment. Detailed work exposure levels and work histories were available. At all exposure levels, there was a statistically significant number of excess respiratory cancers. This study is summarized in the OHEA report, pp. 7-95 to 7-104.

c. Enterline and Marsh (1982) studied 2802 men who had worked at a Tacoma, Washington, smelter for a year or more between 1940 and 1964, with observations through 1976. Individual exposures to airborne arsenic were estimated using work histories and were correlated to levels of arsenic found in urine. A statistically significant increase in respiratory cancers was observed at the higher exposure levels studied. This study is summarized in the OHEA report, pp. 7-118 to 7-128.

d. Brown and Chu (1983 a, b, c) interpreted the data of Lee-Feldstein according to a multi-stage model of carcinogenesis, taking into account exposure rate, durations of exposure, age at initial exposure, and time since cessation of exposure. Brown and Chu's analysis is described in the OHEA report, pp. 7-110 to 7-118.

The CAG used the epidemiological studies of Higgins, Lee-Feldstein, and Enterline and Marsh and the statistical analysis of Brown and Chu in developing its final unit risk estimate for inhalation oncogenic risk, which is described in the OHEA report, pp. 7-130 to 7-135.

Other human epidemiology studies have demonstrated an association between skin cancer in non-occupational populations and high levels of arsenic in drinking water. Persons exposed to arsenicals in medicines have also been shown to be at risk.

The Agency has prepared a risk model for oral exposure to inorganic arsenicals based on an epidemiology study of skin cancer in a section of Taiwan with high arsenic concentrations in well water (Tseng et al., 1968). The EPA Risk Assessment Forum, an Agency-wide task group charged with assessing risk issues, is currently reevaluating this risk model for exposure via the oral route. Their report is expected to be issued in late 1986 or early 1987.

In contrast to the clear association between inorganic arsenicals and cancer in humans, arsenic carcinogenicity in test animals has not been observed in most studies. A few recent reports have noted positive results. Studies in species other than rats have generally shown negative findings. The OHEA document (pp. 7-77 to 7-87) summarizes 32 studies using animals, in which the majority of studies (25) were either negative or inconclusive. Given the extensive amount of information on human exposures, the Agency is not requiring additional animal studies.

4. Mutagenicity. Results from numerous mutagenic and other genotoxic assays provide support to the carcinogenic risk finding. The weight of evidence indicates that arsenate and arsenite can interact with DNA in mammalian somatic and germinal cells and therefore may have the potential to cause heritable effects in humans.

Observed positive effects in various assays have included chromosome-breaking effects, interference with DNA repair mechanisms, direct toxicity to mammalian gonads, and positive effects in selected microbial test systems for mutagenicity.

For example, both the pentavalent and trivalent inorganic arsenicals have induced chromosomal aberrations *in vitro* in human fibroblast cells, Syrian hamster embryo cells, and human peripheral lymphocytes. Results for some studies are dose-related, and arsenites are more potent than arsenates in the induction of chromosomal aberrations in cultured mammalian cells. In addition, among lymphocytes cultured from exposed workers (or from patients undergoing treatment) there is suggestive evidence of chromosomal damage by arsenic *in vivo*. Furthermore, inorganic arsenic may potentiate the effects of chromosome-damaging agents (Sram, 1976; T.-C. Lee et al., 1986).

Evidence of the ability of inorganic arsenic to reach the germ cells (gonads) and produce mutagenic effects in mammals is found in the positive results in the dominant lethal test of Sram and Bencko (1974).

There are no mutagenicity data gaps for arsenic acid.

5. Teratogenicity/Fetotoxicity. Arsenic has been shown to cause teratogenic/fetotoxic effects when tested in animals by routes of exposure not typical of those expected for humans. When tested by routes by which human exposure from pesticide use could be expected, animal studies have been negative or inadequate to demonstrate teratogenicity/fetotoxicity. The Agency is unable to evaluate the risks to humans from available animal studies, and is requiring additional teratogenicity studies.

Sodium arsenate has been shown to produce gross malformations (terata) in hamsters, rats and mice by intravenous and intraperitoneal routes of administration. Increased mortality, increased resorptions and decreased body weights of fetuses have also been observed in these studies.

By contrast, oral (gavage) studies in experimental animals have either failed to produce gross malformations in offspring or have produced only a slightly increased incidence and only at dosage levels that have also caused maternal toxicity:

a. In three mouse studies by Hood et al. using single oral doses of 40-100 mg/kg, 60 mg/kg, and 120 mg/kg on days 7-15 of gestation, there were no teratogenic effects at lower dosages. Slight effects were noted, but only at the 120 mg/kg level, at which there was increased maternal toxicity as well.

b. Kimmel and Fowler reported that administration in the drinking water of 2.7 and 6.5 mg/kg/day of sodium arsenate to pregnant rats throughout pregnancy produced no effects.

All of the oral studies cited above were incomplete or had deficiencies that make them unacceptable to the Agency to fulfill teratogenicity data requirements.

Intravenous, intraperitoneal and oral studies using sodium arsenite have yielded results almost identical to those for sodium arsenate, but at somewhat lower dosage levels.

Intravenous and intraperitoneal administration are not typical of the human exposures likely from pesticide use. Therefore, the Agency is currently unable to assess the risks of teratogenicity/fetotoxicity likely from pesticide use of arsenic acid. Additional studies by the oral route are required to assess teratogenic risks.

Arsenic can cross the placental barrier in humans and has been incriminated in neonatal deaths (Gosselin et al., 1984). Available human studies, however, are limited to epidemiological studies among female smelter workers in Sweden, which showed increased spontaneous abortions and decreased mean birthweights of offspring. These studies were designed, however, to study exposures to a variety of diverse chemicals in the smelter, not arsenicals alone (OHEA, 1984). Thus the effects noted in the study cannot be attributed to arsenical exposure per se.

6. Reproductive effects. There are insufficient data to assess the effects of inorganic arsenicals upon reproductive functions. In light of the Agency's concern about possible teratogenic/fetotoxic effects of arsenicals, a reproduction study also is required.

7. Neurotoxicity. Arsenic is known to cause neurotoxic effects in humans, with the expression and severity of effects dependent upon the route of exposure, level of arsenic, and

duration of exposure. Acute and subchronic exposures typically lead to peripheral neuropathy, distal muscle weakness and loss of sensation, which may progress to paralysis and crippling. Lower exposures and chronic exposures generally have a more gradual onset of similar symptoms.

8. Other observed effects in humans. Other chronic and subchronic effects of inorganic arsenicals that have been observed in humans include:

--Skin toxicity, resulting in hyperpigmentation and disorders such as eczema, redness, keratosis, loss of nails, and swelling, which are reversible if exposure ceases.

--Toxicity to the blood system, resulting in blood dyscrasias of various forms, also reversible if exposure ceases.

--Liver and kidney toxicity, with jaundice, degeneration of the tissues, and cirrhosis.

--Pulmonary system effects, perforation of the nasal septum, and tracheal and bronchial effects.

9. Dietary Exposure and Risks. EPA cannot at this time assess the oncogenic dietary risks associated with pesticide use of arsenic acid.

Arsenic is a constituent of rock and mineral formations in the earth's crust. Weathering of rocks and minerals and decay of plant material appear to be major sources of naturally occurring arsenic in soils. Additional sources of arsenic in the environment are deposition and precipitation of airborne particles from industrial operations.

The determination of dietary exposure resulting from pesticide use is complicated because arsenic acid residues cannot be chemically differentiated from background arsenic. Further, the form and valence of arsenic is subject to change under environmental conditions. Data identifying the species of arsenic residues (pentavalent or trivalent) from applied arsenic acid are not available. Determination of background soil residue levels and identification of the form of those residues are central to the interpretation of arsenic acid residues in food and feed and the risks arising from them.

Residue data are required, and when submitted will be considered in addition to the results of the oral risk model being considered by the Risk Assessment Forum (see III.B.3).

10. Mixer/Loader/Applicator Exposure and Risks. Mixer/loaders of arsenic acid are estimated to have an inhalation exposure of 0.07 mg/hr actual arsenic. This level of exposure results in a lifetime inhalation risk of 10^{-4} to 10^{-5} to mixer/loaders. This risk level approaches that for the general population in areas of high exposure to ambient air levels of arsenic, such as smelters. Inhalation exposure to applicators is negligible.

Average dermal exposure to mixer/loaders is estimated, based on surrogate data from other agricultural uses, to be 530 mg/hr. Dermal exposure to applicators is estimated to be 24 mg/hr. These dermal exposure figures may be revised when the results of the required dermal penetration study and glove permeability information are submitted. Lifetime dermal oncogenic risk cannot be calculated at this time. The risk model now being assessed by the Agency Risk Assessment Forum will be used when completed.

11. Field worker exposure and risks. Arsenic acid is used as a desiccant only on seed crop okra and machine harvested cotton. After application, field workers do not enter treated fields for 4-10 days, and then only to check the edge of the field for readiness for harvesting. Therefore there is no reasonable expectation of post-application exposure. The use is for cotton, primarily in Texas/Oklahoma, and okra in Arizona; the temperature range of 105-115°F usually necessitates the use of enclosed harvesters and combines that are air-filtered and air-conditioned. Thus exposure to harvester operators is negligible.

12. Benefits. Arsenic acid is used in parts of Texas and Oklahoma to desiccate cotton in preparation for harvesting with a cotton stripper. This method of harvest removes a crop (after desiccation) in one sweep--but with more leaves and stems than a cotton picker. Typically about one-third of stripper acreage is chemically treated; arsenic acid accounts for approximately 57% of such treatment.

For the stripper process to function properly, thorough desiccation is needed to allow the cotton bolls to break free readily from the stalk. The entire plant, not just the leaves, must be killed to ensure that green stem trash and newly regrown tissue will not result in excessive moisture in the harvested cotton. Excessive moisture content will lead to deterioration of fiber and seed quality while the cotton is being stored in modules awaiting ginning.

In Texas and Oklahoma, much of the cotton is of a dryland variety, with lower yields per acre than that found in the Mississippi Delta or in irrigated areas of Arizona and California. Use of arsenic acid as a desiccant also permits a short season production system. Desiccation allows early harvest and destruction of crop residues before most insect reproduction, thus diminishing the opportunity for overwintering of boll weevils and pink bollworms. As a consequence, populations of these insects have dropped noticeably and applications of insecticides have been significantly reduced.

Although usage has varied over time, a normal year's usage is about 5.8 million pounds active ingredient for application on 1.3 million acres of cotton. This is about 10% of total U. S. cotton acreage, but about 25% of Texas acreage and 12% of Oklahoma acreage. A significant portion of the Texas acreage is in the Blacklands of the central eastern portion of the state.

Killing frosts or paraquat may be substituted for arsenic acid. In the Texas and Oklahoma Plains, frosts are frequently relied on to desiccate cotton. There are disadvantages, however, in waiting for frosts to prepare cotton for stripping: lint weight drops, lint color darkens, staple length diminishes, and germination decreases. Along the Texas coast and in the Blacklands, the lateness or infrequency of frosts prevents reliance upon nature to desiccate cotton. Instead chemical desiccants are used--usually arsenic acid.

The only registered alternative to arsenic acid is paraquat. The efficacy of paraquat is affected by moisture; if conditions are too moist, the chemical may not completely kill the plant, thus permitting foliar regrowth between treatment and harvest. Along the Texas coast and in the Blacklands, paraquat is less reliable because of the generally moist conditions of those areas. Although paraquat may desiccate as well as arsenic acid under dry weather conditions, it is less consistently effective than arsenic acid. Moreover, it is generally more expensive.

C. OTHER SCIENCE ASSESSMENTS

1. Toxicity to fish and wildlife. Data are not available to completely assess the toxicity of arsenic acid to birds; an avian acute toxicity study is required. However, based on avian dietary studies in mallard duck and bobwhite quail, arsenic acid can be characterized as moderately toxic to birds. An estimated LD-50 based on the LC-50 is 111 mg/kg arsenic.

Arsenic acid is slightly toxic to freshwater fish, with an LC-50 of approximately 60 ppm, and moderately toxic to aquatic invertebrates (LC-50 of 6.5 ppm). An early life stage study for aquatic invertebrates is required to assess the effect of continued low-level exposure to arsenic.

2. Endangered species. The use of arsenic acid as a desiccant of cotton in coastal areas of Texas may pose a hazard to the Attwater's prairie chicken, an endangered species, in Victoria, Refugio and Fort Bend counties. The prairie chicken uses the edges of cotton fields for feeding, not on the cotton plants, but on field edge forbs, seeds, grasses, and insects.

At use levels of 4.4 lbs/A, the Agency estimates that a bird could have an average daily intake of 73 mg/kg, well above the endangered species trigger level of 11.1 mg/kg (1/10 the estimated LD-50 of 111 mg/kg).

Arsenic acid is freely soluble in water, therefore runoff from treated fields may potentially affect endangered aquatic species. Using a 5% runoff factor, the expected environmental concentration of arsenic acid in a one acre pond would be 815 ppb, greater than 1/20 the LC-50 for aquatic invertebrates. There are no endangered aquatic invertebrates in the areas where arsenic acid is used as a desiccant; therefore the risk is minimal.

3. Groundwater. Environmental fate data to assess the potential of arsenic acid or its environmental degradates to contaminate groundwater are sparse. The few data available indicate that the desorption constant of arsenic acid is in the range of 20-100, which suggests low leaching potential. Elevated levels of arsenic have been reported in some groundwaters underlying arsenic acid use areas in Texas. It is impossible to determine whether these residues result from pesticide use or from naturally occurring arsenic.

D. TOLERANCE REASSESSMENT

A tolerance of 4.0 ppm has been established for residues of arsenic acid (expressed as arsenic trioxide As_2O_3) in or on cottonseed (40 CFR 180.180). No tolerances have been established in meat, milk, fat, meat byproducts, and processed food or feed, nor are there any Codex, Canadian, or Mexican cotton tolerances. The use on okra seed crop has been determined to be a nonfood use.

1. Residue Data. EPA has evaluated the residue data supporting the existing tolerance, and has determined that the available residue data, metabolism data (both plant and animal) and analytical methods for residue determinations are inadequate to support the existing tolerance for arsenic acid in cottonseed. The residue data reviewed in support of the tolerance include the following:

a. Analytical methodology for determining the levels of residues of arsenic acid in plants and animals. The analytical methods submitted were considered to be inadequate since they are not capable of distinguishing among the forms of arsenic in plant and animal tissues.

b. Data on the magnitude and levels of residues of arsenic acid in cottonseed. These data were considered inadequate because of inadequate geographical distribution of test sites, lack of information regarding arsenic species present, and insufficient number of tests reflecting the 4-day preharvest interval.

2. Toxicology Data. As discussed earlier, there are few experimental animal studies adequately characterizing the subchronic and chronic effects of arsenic acid, and the dosage levels below which these effects are not observed (the no observed effect level or NOEL). There is, as noted, a substantial body of information on human long-term effects of arsenic. Therefore, chronic feeding studies in animals that would normally be required in support of tolerances are not considered necessary. Reproduction and teratology studies are required using arsenic acid or other soluble pentavalent arsenicals, such as sodium arsenate or arsenic pentoxide.

The Agency has in the interim calculated a preliminary acceptable daily intake (PADI) level from available data on sodium arsenate, a pentavalent salt of arsenic acid. The PADI is based on non-oncogenic effects observed in chronic feeding studies. After review of the required reproduction and teratogenicity studies, an ADI will be established using the study which would result in the most conservative estimate.

Three chronic feeding studies for sodium arsenate are available:

a. A 2-year feeding study on dogs (Byron et al., 1967) using dosage levels of 5, 25, 50, and 125 ppm (expressed as actual arsenic). Effects observed at the highest dosage level (125 ppm) were increased mortality (1/6 dogs died), decreased body weight gain, and mild anemia. The NOEL for this study was 50 ppm (equivalent to 1.25 mg/kg/day actual arsenic).

b. A lifetime study in rats (Kroes et al., 1974), using a single dosage of 416 ppm. Effects observed were decreased body weight gain, decreased food consumption, and increased erythrocyte counts in the female rats. The NOEL, which was not determined in this study, was therefore <416 ppm (equivalent to <20.8 mg/kg/day).

c. A 2-year feeding study on rats (Byron et al, 1967), using dosages of 31.25, 62.5, 125, 250 and 400 ppm. Effects at the 400 ppm level were increased mortality, decreased body weight gain and enlarged and/or thickened common bile ducts in the livers of the treated animals. The NOEL for this study was 62.5 ppm (equivalent to 3.125 mg/kg/day of sodium arsenate).

Of the studies on sodium arsenate, the dog study was selected for the purpose of calculating the PADI because:

--The dog study provided the lowest NOEL (i.e., dogs appear to be more sensitive than rats to sodium arsenate),

--The rat is not the test species of choice because of its unique characteristic of retaining arsenic in the body rather than excreting it rapidly. The results of rat studies are therefore atypical and inappropriate for determination of a NOEL.

3. Provisional Acceptable Daily Intake. The tolerance for arsenic acid is expressed as arsenic trioxide (As_2O_3) (see 40 CFR 180.180). The NOEL from the dog study must also be expressed as As_2O_3 for comparability with arsenic acid.

To convert a dosage of 1.25 mg/kg/day of arsenic (the NOEL in the dog study) to arsenic trioxide, one must use a conversion factor of 1.32:

1.25 mg/kg/day x 1.32 = 1.65 mg/kg/day of As_2O_3.

Using the calculated NOEL of 1.65 mg/kg/day of As_2O_3 and a safety factor of 100, the provisional ADI is

1.65 ÷ 100 = 0.0165 mg/kg/day of AS_2O_3.

For an average 60 kg person, the Maximum Permissible Intake or MPI is

0.0165 mg/kg/day x 60 kg = 0.99 mg/day.

The amount of arsenic (expressed as the trioxide) that is contributed to the average diet from use of arsenic acid on cotton (known as the Theoretical Maximal Residue Contribution or TMRC) is 0.009 mg/day. This represents 0.9% of the amount that is permissible for a 60 kg person.

E. REPORTED PESTICIDE INCIDENTS

The Agency has reviewed information from its Pesticide Incident Monitoring System (PIMS) reports from 1966-1981. In that period of time, 28 incidents involving arsenic acid alone were reported. Eight of these involved use of arsenic acid as a cotton desiccant.

Of the eight incidents identified as relating to cotton desiccant use, one involved a human fatality and two persons hospitalized, three involved cattle, and four involved crop damage from spray drift.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS

1. Special Review. The Agency initiated a Special Review for the non-wood uses of arsenic acid in 1978. The Agency's preliminary determination is projected for issuance in 1987. Until the conclusion of the Special Review, all currently registered products will remain registered.

Rationale: The Agency determined in 1978 (October 18, 1978, 43 FR 48267) that the inorganic arsenicals met or exceeded the risk criteria for Special Review on the basis of oncogenicity, mutagenicity and teratogenicity/fetotoxocity criteria.

2. New uses. No new uses for arsenic acid will be approved until the conclusion of the Special Review.

Rationale: In light of the ongoing Special Review and the concerns it raises about arsenic acid, EPA believes it prudent not to expand the uses or increase potential exposure to arsenic acid.

3. Restricted Use: Arsenic acid products will be restricted to use by certified applicators.

Rationale: The Agency has determined that arsenic acid products exceed the criteria for Restricted Use classification stated in 40 CFR 162.11(c)(2)(ii). First, arsenic acid is highly toxic to humans by the oral route, thus meeting the criterion for restriction on an acute toxicity basis (§ 162.11(c)(2)(ii)(A)). Second, arsenic has been categorized as a Class A oncogen, thus meeting the criterion for restriction on a chronic toxicity basis (§ 162.11(c)(2)(ii)(B)).

EPA believes that, to minimize the risks to mixer/loaders and applicators, use should be limited to persons who have been trained in proper use procedures and exposure reduction measures.

4. Groundwater Concerns: The Agency will not place any restrictions on use of arsenic acid products at this time based upon potential groundwater contamination.

Rationale: Available data indicate that arsenic acid residues have a low leaching potential. Although arsenic has been detected in groundwater, the available data do not permit EPA to determine whether the source of the residues was pesticide use, naturally occurring arsenic in the soil, or arsenic deposited on the soil from non-pesticidal sources. A decision on regulatory action will be deferred until the results of the soil column leaching study and supplemental leaching data specified in Table A are submitted.

5. Reentry Requirements: The Agency will not impose any reentry requirements for the currently registered uses of arsenic acid [i.e., cotton and okra (seed crop)].

Rationale: After spray residues of arsenic acid have dried on the fields, they are not generally dislodgeable. Moreover, workers do not enter the treated fields for 4-10 days, and only to inspect the fields just prior to the projected harvest date to insure that the crop is sufficiently desiccated for harvest. These workers would only be inspecting a limited portion of treated fields near the end of the established preharvest intervals (i.e., 4 and 10 days after treatment for cotton and okra, respectively). Therefore EPA has determined that reentry intervals are not needed.

6. Protective Clothing Requirements: The Agency will require that protective clothing be worn by mixer/loaders and applicators. Product labels will be required to specify that mixer/loaders wear chemical resistant protective suits, gloves and boots and eye protection. Applicators will be required to wear a protective suit. The Agency will also require that a special study on glove permeability be conducted.

Rationale: Arsenic acid end use products are toxic and oncogenic. Protective clothing is necessary to minimize exposure during mixing, loading and application in order to protect against acute toxicity as well as potential oncogenic risk. Eye protection is required for mixer/loaders because the product is an acid. The glove permeability study will permit the Agency to evaluate dermal exposure and risks with protective clothing.

7. Endangered Species Concerns: The Agency will require all end-use products intended for use as a cotton desiccant to contain endangered species labeling to protect the Attwater's Greater Prairie Chicken in Texas. Labeling statements will require users to obtain and review a bulletin on use in areas where the Attwater's Greater Prairie Chicken is found, and, in those areas, not to use arsenic acid. The Agency has included arsenic acid in its cluster of cotton pesticides. The addition of arsenic acid is currently being reviewed by the Office of Endangered Species (OES), U.S. Department of the Interior (USDI). To further evaluate the hazard to birds, including endangered species, the Agency is requiring an avian acute toxicity study and a residue monitoring field study on avian food items associated with cotton fields.

Rationale: The referral to the OES, USDI, and the labeling statements are based upon calculations comparing the expected environmental concentration of arsenic acid with estimated avian toxicity levels. The Agency derived an estimated avian LD_{50} from the avian dietary LC_{50} study. From the use rate of arsenic acid on cotton, EPA calculated the environmental concentration level on various bird feed items around cotton fields. The calculated expected environmental concentration exceeds 1/10 the estimated avian LD-50, and thus arsenic acid exceeds the criterion for referral to OES, USDI for an endangered species opinion.

The Agency is requiring actual residue monitoring of avian feed items and an avian LD-50 study to verify its theoretical calculations. In the interim, endangered species labeling will be used to protect endangered bird species likely to be found in treated areas.

8. Tolerance Reassessment: The Agency will reassess the adequacy of the existing tolerance after required metabolism data and residue data have been submitted. Current grazing/feeding restrictions will remain in effect. The Agency has required residue metabolism studies on cottonseed, ruminants, and poultry, crop residue field trial data on cotton, and processed food/feed data for cottonseed in the Data Call-In (DCI) issued on February 10, 1986.

Rationale: There are insufficient data to determine whether a change in the present tolerance for cottonseed is needed. Available residue data have been determined to be inadequate and additional toxicology data are required.

9. Rotational Crop Label Restrictions: The Agency is not at this time requiring rotational crop restrictions. If required data demonstrate that followup crops take up arsenic residues from soil, rotational crop restrictions or tolerances in those crops may be necessary.

Rationale: The Agency lacks data at the present time to determine whether planting food or feed crops in arsenic acid treated soils would result in illegal residues in these crops. Several factors lead the Agency to believe that rotational crop restrictions are not necessary to prevent illegal residues: (1) Arsenic is bound to soil, thereby limiting its bioavailability in following crops, such that uptake is not expected; and (2) If there were uptake of arsenic in rotational crops, phytotoxicity would occur at very low levels, limiting the potential residues in the plant.

11. Continuation of Registration: While data gaps are being filled, currently registered end-use products (EPs) containing arsenic acid as the sole active ingredient may be sold, distributed, and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration simply because data are missing or are inadequate (see FIFRA sec. 3(c)(2)(B) and 3(c)(7), unless available data indicate that use of the product is likely to cause unreasonable adverse effects on the environment.

Issuance of this Standard provides a mechanism for identifying data needs. After receipt and review of the data, the Agency will determine if additional regulatory changes are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain arsenic acid as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain arsenic acid as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1%.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing arsenic acid provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products only for the commodities listed below. The Use Index lists all registered uses, as well as approved maximum application rates and frequencies.

-Terrestrial, non-domestic, food use on:

Cotton

-Terrestrial, non-domestic, nonfood use on:

Okra (seed crop only)

D. REQUIRED LABELING

All arsenic acid products (manufacturing and end use) must bear appropriate labeling as specified in 40 CFR 162.10. Appendix II contains information on label requirements.

No pesticide product containing arsenic acid may be released for shipment by the registrant after September 30, 1987, unless the product bears an amended label which complies with the requirements of this Standard.

No pesticide product containing arsenic acid may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to be delivered by any person after September 30, 1988, unless the product bears an amended label which complies with the requirements of this Standard.

The following information must appear on the labeling:

1. Ingredients Statement

The ingredient statement for all products must list the active ingredient as "Arsenic acid" and must contain a substatement which indicates the percentage of "Total Arsenic (water soluble), expressed as metallic".

2. Use Pattern Statements

All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites, which are listed in Use Patterns, Section C.3. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in TABLE A for that use pattern.

3. Precautionary Statements for all products.

When mixing/loading or otherwise handling the concentrate wear midforearm to elbow length chemical resistant gloves, chemical resistant shoes or boots, goggles or face shield, and a protective suit which has long sleeves and long pants. The protective suit must be worn over normal work clothes.

4. Precautionary Statements for Manufacturing-Use Products

N/A (none registered for non-wood preservative uses)

5. Precautionary Statements for End-Use Products

All end use products must bear the following statements:

a. RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY AND
ONCOGENICITY

For retail sale to and use only by certified applicators or persons under their direct supervision, and only for those uses covered by the certified applicator's certification.

[The restricted use statement must appear at the top of the front panel of the label.]

b. When applying the diluted spray solution wear a protective suit which has long sleeves and long pants, chemical resistant gloves, and chemical resistant shoes or boots. The protective suit must be worn over normal work clothes.

c. When applying the dilute spray from an enclosed aircraft cockpit or enclosed tractor cab wear an uncontaminated long sleeve shirt and long pants. Any article of clothing worn while applying the product must be cleaned before reusing. Launder workclothes separate from household articles. Clothing which has been drenched or heavily contaminated should be disposed of in accordance with state or local regulations.

d. This pesticide is toxic to wildlife. Do not apply directly to water or wetlands (swamps, bogs, marshes and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes.

e. Cotton desiccant use only: "The use of any pesticide in a manner that may kill or otherwise harm an endangered or threatened species or adversely modify their habitat is a violation of federal laws. The use of this product is controlled to prevent death or harm to endangered or threatened species that occur in the following counties or elsewhere in their range.

Before using this pesticide in the following counties, you must obtain the Cropland Endangered Species Bulletin (EPA/ES-CROP). The use of this pesticide is prohibited in these counties unless specified otherwise in the Bulletin. The EPA Bulletin is available from either your County Agricultural Extension Agent, the Endangered Species Specialist in your State Wildlife Agency Headquarters or the appropriate Regional Office of the U.S. Environmental Protection Agency (EPA). This Bulletin must be reviewed prior to pesticide use and and retained.

Texas Counties	Endangered Species
Fort Bend, Refugio, Victoria	Attwater's Greater Prairie Chicken

f. Do not graze or use treated plants or gin trash for food or forage.

g. (Product name) is injurious to all plant foliage.

h. Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional office for guidance.

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.
2. The data requirements listed in Tables A and B[2]
3. The labeling requirements specified for manufacturing use products in Section IV.
4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

The data requirements listed in Table A.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

a. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

b. If eligible for the formulator's exemption, the data requirements listed in Table C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients. (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. ~~File~~ with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from (or are not specified in) either EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing and await EPA approval, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

F. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made before the deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring.

EPA will view failure to request an extension before the response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. Time extensions may be considered when joint data development is planned, or when the Agency must approve a new or modified protocol before the study can be begun.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

G. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end-use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section IV.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options IV.D.1. (submit data) or IV.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing Arsenic acid as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

   a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

   b. Confidential Statement of Formula (EPA Form 8570-4).

   c. Formulator's Exemption Statement (EPA Form   ), if applicable.

   d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

   a. Application for Pesticide Registration (EPA Form 8570-1).

   b. Two copies of any required product-specific data (See Table B).

   c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

   d. Product Specific Data Report (EPA Form 8580-4).

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing Arsenic Acid in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form), if applicable.

2. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing Arsenic Acid as the sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. Intrastate Products containing Arsenic Acid either as the sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Addresses

The required information must be submitted to the following address:

Richard F. Mountfort PM-23
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

I. DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product
CHOICE = Choice of several test substances on a case-by-case basis

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.
4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such situation will be explained in a footnote to the table.

7. Time frame for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation1/	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	No	N/A	Yes	6 Months2/
61-3 - Discussion of Formation of Impurities	TGAI	All	No	N/A	Yes	6 Months2/
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	All	No	N/A	Yes	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	No	N/A	Yes	6 Months
63-3 - Physical State	TGAI	All	No	N/A	Yes	6 Months
63-4 - Odor	TGAI	All	No	N/A	Yes	6 Months
63-5 - Melting Point	TGAI	All	No	N/A	Yes	6 Months
63-6 - Boiling Point	TGAI	All	No	N/A	Yes	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	No	N/A	Yes	6 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation1/	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-8 - Solubility	TGAI or PAI	All	No	N/A	Yes	6 Months
63-9 - Vapor Pressure	TGAI or PAI	All	No	N/A	Yes	6 Months
63-10 - Dissociation constant	TGAI or PAI	All	No	N/A	Yes	6 Months
63-11 - Octanol/water partition coefficient	PAI	All	No	N/A	Yes	6 Months
63-12 - pH	TGAI	All	No	N/A	Yes	6 Months
63-13 - Storage Stability	TGAI	All	No	N/A	Yes	15 Months
Other Requirements:						
64- 1 - Submittal of samples	TGAI, PAI	All	No	N/A	Yes	6 Months

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1/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

2/ From the date of receipt of the "Data Call-In Notice" for arsenic acid issued 2/10/86.

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.125 Residue Chemistry					
171-2 - Chemical Identity	TGAI	No	---	Yes	---[9]
171-4 - Nature of Residue (Metabolism)					
- Plants	PAIRA	No	---	Yes[3]	---[9]
- Livestock	PAIRA	No	---	Yes[4]	---[9]
171-4 - Residue Analytical Method					
- Plant residues	TGAI	No	---	Yes[5]	---[1,9]
- Animal residues	TGAI	No	---	Yes[5]	---[1,9]
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use					
o Cotton					
-- Crop field trials	TEP	No	---	Yes[2,6]	---[1,9]
-- Processed Food/Feed	EP	No	---	Yes[2,7]	---[1,9]
-- Meat/Milk/Poultry/Eggs	TGAI	No	---	Reserved[2,8]	---

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

§158.125 Residue Chemistry - Continued

1/ It is recommended that the results of the "Nature of Residue (Metabolism)" studies in plants and animals be submitted and found to be acceptable by the Agency prior to the development of an acceptable Analytical Method and that both of these data requirements should be completed prior to completion of the crop field trials.

2/ All residue data requested in this standard must be accompanied by data regarding storage duration and conditions of samples analyzed. These data must be accompanied by data depicting the stability of residues of arsenic acid (total as well as speciated arsenic) under the conditions and for the intervals specified.

3/ Data reflecting the distribution and metabolism of [^{74}As]arsenic acid in cottonseed following foliar desiccant treatment. Samples must also be analyzed using (i) Method I(d) in PAM, Vol. II (A.O.A.C. 14th Ed., § 25.041-25.047) to ascertain its validity for data collection and enforcement purposes, and (ii) an analytical procedure capable of speciating arsenic.

4/ Metabolism studies utilizing ruminants and poultry. Animals must be dosed for three days with [^{74}As]arsenic acid at a concentration in the total diet which will result in sufficient residues in the tissues, milk, and eggs for characterization. Animals must be sacrificed within 24 hours of the final dose (milk and eggs must be collected twice daily). ^{74}As- residues must be characterized in muscle, fat, kidney, liver, milk, and eggs. Samples must also be analyzed using (i) Method I(b) in PAM, Vol. II (A.O.A.C. 14th Ed., § 25.050-25.055) to ascertain its validity for data collection and enforcement purposes, and (ii) an analytical procedure capable of speciating arsenic.

5/ Validated quantitative methods which are capable of speciating arsenic in plant and in animal tissues must be submitted.

6/ Data depicting residues of total arsenic and individual arsenic species (expressed as As and as As_2O_3) in or on cottonseed harvested 4 days after a single application of the 75% SC/L at 1.5 qt./A, applied in 4 gal. water /acre using ground equipment. Tests must be conducted in TX (30%), CA (25%), and MS (11.5%), which represent the major U.S. cotton production regions (Agricultural Statistics, 1984, p. 62); 1983 preliminary cotton production values for each state appear in parentheses. (Note: If this use on cotton is geographically restricted to Texas and Oklahoma, then data from Texas only will be required.) The treatment history of the fields for the past 5 years will be required. Two different groups of treated samples and controls will be required. One group should be known to have been treated with an arsenical pesticide within the past 1 to 2 years; the second group should be known not to have been treated in the past 5 years. Pretreatment soil measurements of total arsenic and individual arsenic species (expressed as As and as As_2O_3) must be obtained from each test site.

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

§158.125 Residue Chemistry - Continued

7/ Data depicting residues of total arsenic and individual arsenic species (expressed as As and as As_2O_3) in gin trash, meal, hulls, crude and refined oil, and soapstock, processed from cottonseed bearing measurable, weathered residues. Should residues concentrate in any of these products, appropriate food/feed additive tolerances must be proposed.

8/ The need for studies regarding the magnitude of the residue in meat, milk, poultry, and eggs will be determined when the requirement for livestock metabolism data has been satisfied.

9/ This data has already been requested in the arsenic acid "Data Call-In Notice" issued 2/10/86. The time frame for submission of this data is as specified in that Notice.

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate[1,2,3]						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B	No	---	No[4]	---
Photodegradation						
161-2 - In water	TGAI or PAIRA	A,B	No	---	No[5]	---
161-3 - On soil	TGAI or PAIRA	A	No	---	No[5]	---
161-4 - In Air	TGAI or PAIRA	A	No	---	No[5]	---
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B	No	---	Yes[6]	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No	---	Yes[7]	27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	N/A[19]	---	---	---	---
162-4 - Aerobic Aquatic	TGAI or PAIRA	N/A[19]	---	---	---	---
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B	No	---	Yes[8,9]	12 Months
163-2 - Volatility (Lab)	TEP	A	No	---	Yes	12 Months
163-3 - Volatility (Field)	TEP	A	No	---	Reserved[10]	---

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate - Continued[1,2,3]						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B	No	---	Yes[11,12]	27 Months
164-2 - Aquatic (Sediment)	TEP	N/A[19]	---	---	---	---
164-3 - Forestry	TEP	N/A[19]	---	---	---	---
164-4 - Combination and Tank Mixes	TEP	---	---	---	No[13]	---
164-5 - Soil, Long-term	TEP	A	No	---	Reserved[14]	---
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	No	---	Yes[15]	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No	---	Reserved[16]	---
165-3 - Irrigated Crops	TEP	N/A[19]	---	---	---	---
165-4 - In Fish Organisms	TGAI or PAIRA	A,B	No	---	Yes[17]	12 Months
165-5 - In Aquatic Non-Target Organisms	TEP	N/A[19]	---	---	---	---
ADDITIONAL STUDIES:						
- Glove Permeability Study	TEP	A,B	No	---	Yes[18]	6 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

§158.130 Environmental Fate - Continued

1/ Because of the unique chemical properties of the arsenic species a complete statement of formula will be required for each TEP. This statement must include forms, quantities, and species of arsenic present.

2/ For all metabolism, dissipation and uptake studies, methodologies should be designed such that natural soil arsenic may be distinguished from arsenic acid residues.

3/ Due to the non-standard nature of the data requirements to be imposed under this Registration Standard it is strongly recommended that protocols for each study be submitted prior to initiation of the study.

4/ No additional data required. Arsenic acid (pure active ingredient) is chemically defined as a weak triprotic inorganic acid. Hydrolysis of such acids occurs as deprotonation and will occur upon mixing with water. The pK's for the three protons are 2.25, 6.77, and 11.60. Products will be the proton and the pentavalent arsenate anion form or a partially protonated anion depending on the system pH.

5/ No additional data required. Due to the known photochemical characteristics of the compound no useful environmental fate information would be obtained from a photolysis study.

6/ Study should be designed as a confined dissipation study. A minimum of three soils will be necessary to fullfill these requirements. At least two of the soils used in these studies must be representative of the area of use. Data needed include the form, availability, and rates of dissipation and/or occlusion of arsenic acid residues. Species determination of available arsenic acid residues may be necessary.

7/ Data required must define the form, availability, and rates of dissipation and occlusion of arsenic acid residues. Additionally, data are required to determine the degree of anaerobicity (Eh) of the test system. Species determination of available arsenic acid residues will be necessary since arsenite (As^{+3}) formation occurs under anaerobic conditions.

8/ Soil column leaching study required. See Subdivision N §163-1 for study specifics.

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

§158.130 Environmental Fate - Continued

9/ Additional study required using soils representative of the areas of arsenic acid use:

a. At least three soil core sites should be examined for background As levels before desiccant application;

b. A conservative water tracer such as chloride ion should be added to the field on the same day as the pesticide is applied;

c. All soil cores should be taken and analyzed in continuous six inch segments until the zone of maximum leaching is established;

d. Arsenic acid residues at the zone of maximum leaching should be speciated and quantified.

10/ Data requirements reserved pending the results of an acceptable laboratory volatility study.

11/ Establishment of preapplication soil background levels is required for interpretation of this data.

12/ Speciation of available As residues will be necessary for determination of environmental fate of arsenic acid residues.

13/ Data requirements for combination products and tank mix uses are not being imposed for this Standard because no such products or tank mix uses exist for the cotton and okra uses.

14/ Data requirements are reserved pending results of aerobic soil metabolism and terrestrial field dissipation studies.

15/ Crops used for these studies should be representative of those that are normally rotated into arsenic acid treated fields.

16/ Data required unless confined study (165-1) indicates no uptake of arsenic acid residues.

17/ Baseline or background arsenic levels in test organisms must be established prior to the addition of the test material.

18/ A glove permeability study is required. The study should be conducted in accordance with ASTM 739-81 - Standard Test Method for Resistance of Protective Materials to Permeation by Hazardous Liquid Chemicals. It is strongly suggested that a test protocol be submitted prior to initiation of this study.

19/ Data is only required for aquatic and/or forestry use patterns, as specified in §158.130.

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

Date Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rodent	TGAI	A,B	No	---	Yes[2]	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A,B	No	---	Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rodent	TGAI	A,B	No	---	Yes[2]	9 Months
81-7 - Delayed Neurotoxicity - Hen	TGAI	A,B	No	---	No[1]	---

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

Date Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted	Time Frame for Submission
§158.135 Toxicology						
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding: - Rodent, and	TGAI	A	Yes	00159870	No	---
- Non-rodent (Dog)	TGAI	A	Yes	00159870	No	---
82-2 - 21-Day Dermal - Rabbit	TGAI	A	Yes	00159870	No	---
82-3 - 90-Day Dermal - Rabbit	TGAI	A	No	---	No[1/]	---
82-4 - 90-Day Inhalation: - Rat	TGAI	A	No	---	No[1/]	---
82-5 - 90-Day Neurotoxicity: - Hen	TGAI	A	No	---	No[1/]	---
-Mammal	TGAI	A	Yes	00159870	No	---

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
CHRONIC TESTING:						
83-1 - Chronic Toxicity - 2 species:						
- Rodent, and	TGAI	A	Yes	00159870	No	---
- Non-rodent (Dog)	TGAI	A	Yes	00159870	No	---
83-2 - Oncogenicity - 2 species:						
- Rat (preferred), and	TGAI	A	Yes[4]	00159870	No	---
- Mouse (preferred)	TGAI	A	Yes[4]	00159870	No	---
83-3 - Teratogenicity - 2 species:						
- Rodent	TGAI	A	No	---	Yes[3]	15 Months
- Rabbit	TGAI	A	No	---	Yes	15 Months
83-4 - Reproduction - Rodent 2-generation	TGAI	A	No	---	Yes[2]	39 Months
MUTAGENICITY TESTING						
84-2 - Gene Mutation (Ames Test)	TGAI	A,B	Yes	00159870	No	---
84-2 - Structural Chromosomal Aberration	TGAI	A,B	Yes	00159870	No	---
84-4 - Other Genotoxic Effects	TGAI	A,B	Yes	00159870	No	---

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA	A	Yes	00159870	No	---
85-2 - Dermal Penetration	Choice	A	No	---	Yes	12 Months
86-1 - Domestic Animal Safety	Choice	A	Yes	00159870	No	---

1/ Data base (OHEA document - 00159870) and exposure scenario do not mandate testing at this time.

2/ A rodent species other than the rat is required since rats are known to be anomalous with respect to the pharmacokinetics of arsenic.

3/ A mouse or hamster is required since rats are known to be anomalous with respect to the pharmacokinetics of arsenic.

4/ Human epidemiology studies were used in place of animal studies.

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	N/A[1/]	---	---	---	---
132-1 - Soil Dissipation	TEP	N/A[1/]	---	---	---	---
133-3 - Dermal Exposure	TEP	N/A[1/]	---	---	---	---
133-4 - Inhalation Exposure	TEP	N/A[1/]	---	---	---	---
§158.142 Spray Drift						
201-1 - Droplet Size Spectrum	TEP	A,B	No	---	Yes	9 Months
202-1 - Drift Field Evaluation	TEP	A,B	No	---	Yes	9 Months

[1/] Substantial human exposure to the pesticide is not likely to occur.

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
70-1 - Special Test	TEP	A	No	---	Yes[1/]	16 Months
71-1 - Acute Avian Oral Toxicity	TGAI	A,B	No	---	Yes	9 Months
71-2 - Avian Subacute Dietary Toxicity						
- Upland Game Bird, and	TGAI	A,B	Yes	00121618	No	---
- Waterfowl	TGAI	A,B	Partial	00106855	Yes[7/]	9 Months
71-3 - Wild Mammal Toxicity	TGAI	A,B	No	---	No	---
71-4 - Avian Reproduction						
- Upland Game Bird, and	TGAI	A,B	No	---	No	---
- Waterfowl	TGAI	A,B	No	---	No	---
71-5 - Simulated Field Testing						
- Mammals, and	TEP	A,B	No	---	No	---
- Birds	TEP	A,B	No	---	Reserved[3/]	---
- Actual Field Testing						
- Mammals, and	TEP	A,B	No	---	No	---
- Birds	TEP	A,B	No	---	Reserved[3/]	---

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish Toxicity - Coldwater Fish Species, and	TGAI	A,B	Yes	GS0389-002	No	---
- Warmwater Fish Species	TGAI	A,B	Partial	00119999	Yes 2/	9 Months
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,B	Yes	GS0389-003	No	---
72-3 - Acute Toxicity to Estuarine and Marine Organisms - Fish	TGAI	A	No	---	Reserved 4/	---
- Mollusk	TGAI	A	No	---	Reserved 4/	---
- Shrimp	TGAI	A	No	---	Reserved 4/	---
72-4 - Fish Early Life Stage	TGAI	N/A	No	---	No 5/	---
Aquatic Invertebrate Life Cycle	TGAI	A	No	---	Yes 5/	15 Months
72-5 - Fish - Life-Cycle	TGAI	A	No	---	Reserved 6/	---

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
72-6 - Aquatic Organism Accumulation						
- Crustacean	TGAI	A	No	Reserved[6/]	---	---
- Fish	TGAI	A	No	Reserved[6/]	---	---
- Insect Nymph	TGAI	A	No	Reserved[6/]	---	---
- Mollusk	TGAI	A	No	Reserved[6/]	---	---
72-7 - Simulated Field Testing - Aquatic Organisms	TEP	A	No	Reserved[6/]	---	---
- Actual Field Testing - Aquatic Organisms	TEP	A	No	Reserved[6/]	---	---

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

§158.145 Wildlife and Aquatic Organisms - Continued

1/ Residue monitoring field study on avian food items associated with cotton fields in Texas. Carcasses should be recorded when found. Food items tested should include grasses, forbs (such as, buttonweed, doveweed and ruellia), seed-producing plants and dead insects. Protocols must be submitted within 3 months.

2/ This study may be repaired by submission of missing data/information: dissolved oxygen and pH values during the test; data on negative controls; and 96-hour mortality data. If these data cannot be supplied, a new study is required in order to fulfill this data requirement.

3/ Studies may be required upon receipt of avian acute oral LD^{50} and the Special Test (70-1 described in footnote 1).

4/ Testing on marine organisms is reserved pending receipt of acute freshwater fish testing results (72-1).

5/ Chronic testing on freshwater aquatic species is being required because the estimated environmental concentration in water exceeds 0.01 the LC50. Only the aquatic invertebrate life cycle test is being required because acute toxicity data indicate that the aquatic invertebrates are more sensitive than fish to arsenic acid.

6/ Test reserved pending outcome of the aquatic invertebrate life cycle test.

7/ Addition of arsenic acid to the diet resulted in food aversion in the submitted study. Either a repellency test, using treated diet and untreated nonpreferred food as choices, or an additional dietary study using another species of waterfowl must be performed.

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.150 Plant Protection						
121-1 - TARGET AREA PHYTOTOXICITY	EP	A,B	No	---	No[1]	---
NONTARGET AREA PHYTOTOXICITY						
TIER I						
122-1 - Seed Germination/ Seedling Emergence	TGAI	B	No	---	No[2]	---
122-1 - Vegetative Vigor	TGAI	B	No	---	No[2]	---
122-2 - Aquatic Plant Growth	TGAI	B	No	---	No[2]	---
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI	B	No	---	No[3]	---
123-1 - Vegetative Vigor	TGAI	B	No	---	No[3]	---
123-2 - Aquatic Plant Growth	TGAI	B	No	---	No[3]	---
TIER III						
124-1 - Terrestrial Field	TEP	B	No	---	No[3]	---
124-2 - Aquatic Field	TEP	B	No	---	No[3]	---

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

§158.150 Plant Protection

1/ These data are only required when target area phytotoxicity is one of the issues involved in initiating the Special Review.

2/ Data requirement is not relevant to the okra use.

3/ Test is not required because corresponding lower tier tests are not required.

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.155 Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honey bee acute contact toxicity	TGAI	A,B	No	---	Yes	9 Months
141-2 - Honey bee - toxicity of residues on foliage	TEP	A,B	No	---	Reserved[1]	---
141-4 - Honey bee subacute feeding study	(Reserved)[2]					---
141-5 - Field testing for pollinators	TEP	A,B	No	---	Reserved[1]	---
NONTARGET INSECT TESTING - AQUATIC INSECTS:						
142-1 - Acute toxicity to aquatic insects	(Reserved)[3]	---	---	---	---	---
142-2 - Aquatic insect life-cycle study	(Reserved)[3]	---	---	---	---	---
142-3 - Simulated or actual field testing for aquatic insects	(Reserved)[3]	---	---	---	---	---
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	(Reserved)[3]	---	---	---	---	---

TABLE A
GENERIC DATA REQUIREMENTS FOR ARSENIC ACID

§158.155 Nontarget Insect

1/ Requirement reserved pending receipt of results from Honeybee acute contact study.

2/ Reserved pending development of test methodology.

3/ Reserved pending Agency decision as to whether the data requirement should be established.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ARSENIC ACID

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?1/	Bibliographic Citation1/	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	No	N/A	Yes	6 Months2/
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	No	N/A	Yes	6 Months2/
61-3 - Discussion of Formation of Impurities	MP	All	No	N/A	Yes	6 Months2/
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	All	No	N/A	Yes	12 Months
62-2 - Certification of Limits	MP	All	No	N/A	Yes	12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	All	No	N/A	Yes	12 Months
Physical and Chemical Characteristics						
63-2 - Color	MP	All	No	N/A	Yes	6 Months
63-3 - Physical State	MP	All	No	N/A	Yes	6 Months
63-4 - Odor	MP	All	No	N/A	Yes	6 Months

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ARSENIC ACID

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?1/	Bibliographic Citation1/	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	MP	All	No	N/A	Yes	7 Months
63-12 - pH	MP	All	No	N/A	Yes	7 Months
63-14 - Oxidizing or Reducing Action	MP	All	No	N/A	Yes	7 Months
63-15 - Flammability	MP	All	No	N/A	Yes	7 Months
63-16 - Explodability	MP	All	No	N/A	Yes	7 Months
63-17 - Storage Stability	MP	All	No	N/A	Yes	16 Months
63-18 - Viscosity	MP	All	No	N/A	Yes	7 Months
63-19 - Miscibility	MP	All	No	N/A	Yes	7 Months
63-20 - Corrosion Characteristics	MP	All	No	N/A	Yes	7 Months
Other Requirements:						
64- 1 - Submittal of samples	MP	All	No	N/A	Yes	7 Months

1/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each manufacturing use product. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

2/ From the date of receipt of the Data Call-In Notice for arsenic acid issued 2/10/86.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ARSENIC ACID

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral Toxicity - Rodent	MP	A,B	No	---	Yes[1/]	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	MP	A,B	No	---	Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rodent	MP	A,B	No	---	Yes[1/]	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	A,B	No	---	Yes	9 Months
81-5 - Primary Dermal Irritation - Rabbit	MP	A,B	No	---	Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	A,B	No	---	Yes	9 Months

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1/ A rodent species other than the rat is required since rats are known to be anomalous with respect to the pharmacokinetics of arsenic.

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit'area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-8

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC_{50}	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter.	From 2. thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LD_{50}	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with differen registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plactic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. USE INDEX APPENDIX

ARSENIC ACID*

TYPE PESTICIDE: Desiccant (Refer also to Fungicide entry for wood preservatives)

FORMULATIONS: SC/L (15.7 lb/gal or 75% a.i., 75%)

GENERAL WARNINGS AND LIMITATIONS: RESTRICTED USE PESTICIDE. For retail sale to and use only by certified applicators or persons under their direct supervision, and only for those uses covered by the certified applicator's certification. Arsenic acid is used as a preharvest desiccant in (stripper harvested) cotton and in okra grown for seed. Apply on clear days when the average temperature is 80 F (26.7 C) or higher. Do not use in galvanized metal containers or spray equipment, as highly toxic arsine gas may be formed. Avoid spray drift to desirable plants or to areas and buildings occupied by humans, animals, or poultry. Do not graze or use treated plants or gin trash for food or forage. This pesticide is toxic to wildlife. Do not apply directly to water or wetlands (swamps, bogs, marshes and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes. When mixing/loading or otherwise handling the concentrate wear midforearm to elbow length chemical resistant gloves, chemical resistant shoes or boots, goggles or face shield, and a protective suit which has long sleeves and long pants. When applying the diluted spray solution wear a protective suit which has long sleeves and long pants, chemical resistant gloves, and chemical resistant shoes or boots. The protective suit must be worn over normal work clothes. When applying the dilute spray from an enclosed aircraft cockpit or enclosed tractor cab wear an uncontaminated long sleeve shirt and long pants. Any article of clothing worn while applying product must be cleaned before reusing. Launder work clothes separately from household articles. Clothing which has been drenched or heavily contaminated should be disposed of in accordance with state or local regulations.
The use of any pesticide in a manner that may kill or otherwise harm an endangered or threatened species or adversely modify their habitat is a violation of federal laws. The use of this product is controlled to prevent death or harm to endangered or threatened species that occur in the following counties or elsewhere in their range. Before using this pesticide in the following counties, you must obtain the Cropland Endangered Species Bulletin (EPA/ES-CROP). The use of this pesticide is prohibited in these counties unless specified otherwise in the Bulletin. The EPA Bulletin is available from either your County Agricultural Extension Agent, the Endangered Species Specialist in your State Wildlife Agency Headquarters or the appropriate Regional Office of the U.S. Environmental Protection Agency (EPA). THIS BULLETIN MUST BE REVIEWED PRIOR TO PESTICIDE USE.

SPECIES	STATE	COUNTY
Attwater's Greater Prairie Chicken	TX	Fort Bend, Refugio and Victoria

*orthoarsenic acid

GENERAL WARNINGS AND LIMITATIONS (continued)

Bee Caution:
Arsenic acid is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treated area.

TIME REQUIRED FOR CONTROL: Four to 10 days.

PHYTOTOXICITY TO CROPS: Kills leaves rapidly and eliminates leaf regrowth.

MODE OF ACTION: Reacts with proteins, causing denaturation of protoplasm. Inactivates enzymes and decreases rate of respiration.

PLANT REGULATOR CLAIMS:

PZZZZZB Desiccant

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	TERRESTRIAL FOOD CROP	
	(Agricultural Crops)	
/28007AA	Cotton	4.0 ppm (cotton, seed) 4 day preharvest interval. Do not graze or use treated plants or gin trash for feed or forage. Do not apply to cotton that is to be harvested by hand or by spindle-type pickers. Do not apply more than 6 pounds active ingredient per acre to avoid excessive residues on raw cottonseed. General Information: Use as a primary treatment only for cotton that is to be stripped mechanically. May be applied to kill new leaf growth prior to picking after application of a defoliant. Do not tank mix with other defoliants.
	6 (15.7 lb/gal SC/L) 004581-00231 or 1-1.5 qt product/A (75% SC/L) 007401-00184	Preharvest desiccant. Broadcast. Apply uniformly in 4 to 10 gallons of finished spray per acre. Do not apply until cotton is mature and all bolls expected to produce lint are fully opened.
	TERRESTRIAL NONFOOD CROP	
	(Agricultural Crops)	
	Okra (grown for seed production only)	N.F. Do not graze or use seed for food, feed, or processing.
	[SLN] 6 (15.7 lb/gal SC/L)	SLN - Use limited to AZ. Preharvest. Broadcast. Apply in 4 to 10 gallons of finished spray, 10 to 14 days before harvest.

Listing of Registered Pesticide Products by Formulation

&275.0015 75% soluble concentrate/liquid
arsenic acid (006801)
003008-00043* 007401-00184 007401-00195 007401-00200
*registrant has requested voluntary cancellation.

&275.0015 75% (15.7 lb/gal) soluble concentrate/liquid
arsenic acid (006801)
000400-00230** 004581-00231 019713-00103# 020004-00003**
**suspended
#scheduled to be suspended

(004581-00231) AZ790038

IV. BIBLIOGRAPHY APPENDICES

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Arsenic Acid Standard

MRID	CITATION
00106855	Goldenthal, E.; Wazeter, F.; Dean, W. (1973) Dietary Toxicity (LC50) Study in Mallard Ducks: Arsenic Acid--75%: 316-004. (Unpublished study received Jun 28, 1974 under 4581-231; prepared by International Research and Development Corp., submitted by Agchem Div., Pennwalt Corp., Philadelphia, PA; CDL:026041-B)
00119999	McCann, J.; Pitcher, F. (1973) Delta Brand Arsenic Acid: Bluegill, Lepomis macrochirus: Test No. 539. (Unpublished study received Apr 4, 1973 under 295-6; prepared by Pesticides Regulation Div., Animal Biology Laboratory, submitted by U.S. Environmental Protection Agency, Beltsville, MD; CDL:128268-A)
00121618	Goldenthal, E.; Wazeter, F.; Dean, W. (1974) Dietary Toxicity (LC-50) Study in Bobwhite Quail: 316-004. (Unpublished study received Apr 9, 1974 under 7401-184; prepared by International Research and Development Corp., submitted by Voluntary Purchasing Group, Inc., Bonham, TX; CDL:128273-A)
00159870	Jacobson-Kram, D.; Mushak, P.; Piscator, M.; et al. (1984) Health Assessment Document for Inorganic Arsenic: Final Report: EPA-600/8-83-021F. Washington, DC: Environmental Protection Agency. 347 p.
GS0389-002	U.S. Environmental Protection Agency (1980) 96-hr LC50 of Arsenic Acid in Rainbow Trout: Static Jar Test #2446. Unpublished report prepared by Chemical and Biological Investigations Branch. 1 p.
GS0389-003	U.S. Environmental Protection Agency (1980) 48-hr EC50 of Arsenic Acid in Daphnia magna: Static Jar Test #2448. Unpublished report prepared by Chemical and Biological Investigations Branch. 1 p.

V. FORMS APPENDICES

OMB Approval No. 2000-0468

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	**GUIDANCE DOCUMENT DATE** **ACTIVE INGREDIENT**
NAME OF FIRM	**EPA COMPANY NUMBER**

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.____________________ Date ____________________

Guidance Document for ____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by: Citing MRID Number or EPA Accession Number	I am complying with data requirements by: Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by: Citing MRID Number or EPA Accession Number	I am complying with data requirements by: Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

FORMULATOR'S EXEMPTION STATEMENT
(40 CFR 152.85)

EPA File Symbol/Reg. No. ______________ Product Name ______________________

Applicant's Name and Address ____

____

____

____

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) This product contains the active ingredient(s): ______________

____

____

(2) Each active ingredient listed in paragraph (1) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA sec. 3, and which is purchased by us from another producer.

(3) Indicate by circling (A) or (B) below which paragraph applies:

(A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

(B) The Confidential Statement of Formula dated __________ on file with the EPA is complete, current and accurate and contains the information required on the current CSF Form No. 8570-4. The registered source(s) of the active ingredient(s) listed in paragraph (1) is/are listed below:

Active ingredient	Source: Product name and Reg. No.

Signature ______________________

Date ______________ Title ______________________

EPA Form (April 1985)